

NICORETTE WHITE ICE MINT- nicotine polacrilex gum, chewing
NICORETTE ORIGINAL- nicotine polacrilex gum, chewing
NICORETTE CINNAMON SURGE- nicotine polacrilex gum, chewing
NICORETTE FRESH MINT- nicotine polacrilex gum, chewing
NICORETTE MINT- nicotine polacrilex gum, chewing
NICORETTE SPEARMINT BURST- nicotine polacrilex gum, chewing
GlaxoSmithKline Consumer Healthcare Holdings (US) LLC

Drug Facts

Active ingredient (in each chewing piece)

Nicotine polacrilex (equal to 2 mg nicotine)

Nicotine polacrilex (equal to 4 mg nicotine)

Purpose

Stop smoking aid

Use

- reduces withdrawal symptoms, including nicotine craving, associated with quitting smoking

Warnings

If you are pregnant or breast-feeding, only use this medicine on the advice of your health care provider.

Smoking can seriously harm your child. Try to stop smoking without using any nicotine replacement medicine. This medicine is believed to be safer than smoking. However, the risks to your child from this medicine are not fully known.

Ask a doctor before use if you have

- a sodium-restricted diet
- heart disease, recent heart attack, or irregular heartbeat. Nicotine can increase your heart rate.
- high blood pressure not controlled with medication. Nicotine can increase blood pressure.
- stomach ulcer or diabetes
- history of seizures

Ask a doctor or a pharmacist before use if you are

- using a non-nicotine stop smoking drug
- taking a prescription medicine for depression or asthma. Your prescription dose may need to be adjusted.

Stop use and ask a doctor if

- mouth, teeth or jaw problems occur
- irregular heartbeat or palpitations occur

- you get symptoms of nicotine overdose such as nausea, vomiting, dizziness, diarrhea, weakness and rapid heartbeat
- **(For Cinnamon Surge)** oral blistering occurs
- you have symptoms of an allergic reaction (such as difficulty breathing or rash)

Keep out of reach of children and pets.

Pieces of nicotine gum may have enough nicotine to make children and pets sick. Wrap used pieces of gum in paper and throw away in the trash. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions (2 mg)

- **if you are under 18 years of age, ask a doctor before use**
- before using this product, read the enclosed User's Guide for complete directions and other important information
- begin using the gum on your quit day
- **if you smoke your first cigarette within 30 minutes of waking up**, use 4 mg nicotine gum
- **if you smoke your first cigarette more than 30 minutes after waking up**, use 2 mg nicotine gum according to the following 12 week schedule:

| Weeks 1 to 6 | Weeks 7 to 9 | Weeks 10 to 12 |
|----------------------------|----------------------------|----------------------------|
| 1 piece every 1 to 2 hours | 1 piece every 2 to 4 hours | 1 piece every 4 to 8 hours |

- nicotine gum is a medicine and must be used a certain way to get the best results
- chew the gum slowly until it tingles. Then park it between your cheek and gum. When the tingle is gone, begin chewing again, until the tingle returns.
- repeat this process until most of the tingle is gone (about 30 minutes)
- do not eat or drink for 15 minutes before chewing the nicotine gum, or while chewing a piece
- to improve your chances of quitting, use at least 9 pieces per day for the first 6 weeks
- if you experience strong or frequent cravings, you may use a second piece within the hour. However, do not continuously use one piece after another since this may cause you hiccups, heartburn, nausea or other side effects.
- do not use more than 24 pieces a day
- it is important to complete treatment. If you feel you need to use the gum for a longer period to keep from smoking, talk to your health care provider.

Directions (4 mg)

- **if you are under 18 years of age, ask a doctor before use**
 - before using this product, read the enclosed User's Guide for complete directions and other important information
 - begin using the gum on your quit day
 - **if you smoke your first cigarette more than 30 minutes after waking up**, use 2 mg nicotine gum
 - **if you smoke your first cigarette within 30 minutes of waking up**, use 4 mg nicotine gum according to the following 12 week schedule:
-

| Weeks 1 to 6 | Weeks 7 to 9 | Weeks 10 to 12 |
|----------------------------|----------------------------|----------------------------|
| 1 piece every 1 to 2 hours | 1 piece every 2 to 4 hours | 1 piece every 4 to 8 hours |

- nicotine gum is a medicine and must be used a certain way to get the best results
- chew the gum slowly until it tingles. Then park it between your cheek and gum. When the tingle is gone, begin chewing again, until the tingle returns.
- repeat this process until most of the tingle is gone (about 30 minutes)
- do not eat or drink for 15 minutes before chewing the nicotine gum, or while chewing a piece
- to improve your chances of quitting, use at least 9 pieces per day for the first 6 weeks
- if you experience strong or frequent cravings, you may use a second piece within the hour. However, do not continuously use one piece after another since this may cause you hiccups, heartburn, nausea or other side effects.
- do not use more than 24 pieces a day
- it is important to complete treatment. If you feel you need to use the gum for a longer period to keep from smoking, talk to your health care provider

Other information (White Ice Mint)

- **(2 mg) each piece contains:** calcium 94 mg, sodium 11 mg
- **(4 mg) each piece contains:** calcium 94 mg, sodium 13 mg
- store at 20 - 25°C (68 - 77°F)
- protect from light

Other information (Original)

- **each piece contains:** calcium 117 mg, sodium 13 mg
- store at 20 - 25°C (68 - 77°F)
- protect from light

Other information (Cinnamon Surge)

- **(2 mg) each piece contains:** calcium 94 mg, sodium 11 mg
- **(4 mg) each piece contains:** calcium 94 mg, sodium 13 mg
- store at 20 - 25°C (68 - 77°F)
- protect from light

Other information (Fresh Mint)

- **(2 mg) each piece contains:** calcium 94 mg, sodium 11 mg
- **(4 mg) each piece contains:** calcium 94 mg, sodium 13 mg
- store at 20 - 25°C (68 - 77°F)
- protect from light

Other information (Mint)

- **(2 mg) each piece contains:** calcium 94 mg, sodium 13 mg

- **(4 mg) each piece contains:** calcium 94 mg, sodium 14 mg
- store at 20 - 25°C (68 - 77°F)
- protect from light

Other information (Spearmint Burst)

- **(2 mg) each piece contains:** calcium 94 mg, sodium 11 mg
- **(4 mg) each piece contains:** calcium 94 mg, sodium 13 mg
- store at 20 - 25°C (68 - 77°F)
- protect from light

Inactive ingredients (White Ice Mint)

each 2 mg piece contains: acesulfame potassium, carnauba wax, edible ink, flavor, gum base, hypromellose, magnesium oxide, menthol, peppermint oil, polysorbate 80, sodium bicarbonate, sodium carbonate, starch, sucralose, titanium dioxide, xylitol

each 4 mg piece contains: acesulfame potassium, carnauba wax, D&C yellow #10 Al. lake, edible ink, flavor, gum base, hypromellose, magnesium oxide, menthol, peppermint oil, polysorbate 80, sodium carbonate, starch, sucralose, titanium dioxide, xylitol

Inactive ingredients (Original)

each 2 mg piece contains: flavors, glycerin, gum base, sodium bicarbonate, sodium carbonate, sorbitol

each 4 mg piece contains: D&C yellow #10, flavors, glycerin, gum base, sodium carbonate, sorbitol

Inactive ingredients (Cinnamon Surge)

each 2 mg piece contains: acacia, acesulfame potassium, carnauba wax, edible ink, gum base, hypromellose, magnesium oxide, menthol, natural and artificial cinnamon flavors, peppermint oil, polysorbate 80, sodium bicarbonate, sodium carbonate, sucralose, titanium dioxide, xylitol

each 4 mg piece contains: acacia, acesulfame potassium, carnauba wax, D&C yellow #10 Al. lake, edible ink, gum base, hypromellose, magnesium oxide, menthol, natural and artificial cinnamon flavors, peppermint oil, polysorbate 80, sodium carbonate, sucralose, titanium dioxide, xylitol

Inactive ingredients (Fresh Mint)

each 2 mg piece contains: acacia, acesulfame potassium, carnauba wax, edible ink, gum base, magnesium oxide, menthol, peppermint oil, sodium bicarbonate, sodium carbonate, titanium dioxide, xylitol

each 4 mg piece contains: acacia, acesulfame potassium, carnauba wax, D&C yellow #10 Al. lake, edible ink, gum base, magnesium oxide, menthol, peppermint oil, sodium carbonate, titanium dioxide, xylitol

Inactive ingredients (Mint)

each 2 mg piece contains: acesulfame potassium, gum base, magnesium oxide, menthol, peppermint oil, sodium bicarbonate, sodium carbonate, xylitol

each 4 mg piece contains: acesulfame potassium, D&C yellow #10 Al. lake, gum base, magnesium oxide, menthol, peppermint oil, sodium carbonate, xylitol

Inactive ingredients (Spearmint Burst)

each 2 mg piece contains: acacia, acesulfame potassium, carnauba wax, edible ink, flavors, gum base, hypromellose, magnesium oxide, menthol, peppermint oil, polysorbate 80, sodium bicarbonate, sodium carbonate, sucralose, titanium dioxide, xylitol

each 4 mg piece contains: acacia, acesulfame potassium, carnauba wax, D&C yellow #10 Al. lake, edible ink, flavors, gum base, hypromellose, magnesium oxide, menthol, peppermint oil, polysorbate 80, sodium carbonate, sucralose, titanium dioxide, xylitol

Questions and comments?

call toll-free **1-800-419-4766**

Additional information found on packaging

TO INCREASE YOUR SUCCESS IN QUITTING:

1. You must be motivated to quit.
2. **Use Enough** – Chew **at least 9 pieces** of Nicorette gum per day during the first six weeks.
3. **Use Long Enough** – Use Nicorette gum for the full 12 weeks.
4. **Use with a support program** as directed in the enclosed User's Guide.

To remove the gum, tear off single unit.

Peel off backing, starting at corner with loose edge.

Push gum through foil.

- **not for sale to those under 18 years of age**
- **proof of age required**
- **not for sale in vending machines or from any source where proof of age cannot be verified**

This product is protected in sealed blisters. **Do not use if individual blisters or printed backings are broken, open, or torn.**

Distributed by

GSK Consumer Healthcare

Warren, NJ 07059

Made in Sweden

For more information and for a FREE individualized stop smoking program, please visit www.Nicorette.com or see inside for more details.

Principal Display Panel

NDC 0135-0474-02

Nicorette®

nicotine polacrilex gum, 2 mg • stop smoking aid

Gum

Coated

FOR BOLD FLAVOR

White Ice Mint[®]

2 mg

FOR THOSE WHO SMOKE THEIR FIRST CIGARETTE MORE THAN 30 MINUTES AFTER WAKING UP.

If you smoke your first cigarette **WITHIN 30 MINUTES** of waking up, use Nicorette[®] 4 mg Gum **100 PIECES, 2 mg EACH**

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30462XG



Principal Display Panel

NDC 0135-0475-02

Nicorette[®]

nicotine polacrilex gum, 4 mg • stop smoking aid

Gum

Coated

FOR BOLD FLAVOR

White Ice Mint[®]

4 mg

FOR THOSE WHO SMOKE THEIR FIRST CIGARETTE WITHIN 30 MINUTES OF WAKING UP.

If you smoke your first cigarette **MORE THAN 30 MINUTES** after waking up, use Nicorette 2 mg Gum

100 PIECES, 4 mg EACH

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30463XG



Principal Display Panel

NDC 0135-0157-07

Nicorette[®]

nicotine polacrilex gum, 2 mg • stop smoking aid

Gum

Original

2 mg

FOR THOSE WHO SMOKE THEIR FIRST CIGARETTE MORE THAN 30 MINUTES AFTER WAKING UP.

If you smoke your first cigarette **WITHIN 30 MINUTES** of waking up, use Nicorette 4mg Gum
110 PIECES, 2 mg EACH

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29545XG



Principal Display Panel

NDC 0135-0158-07

Nicorette®

nicotine polacrilex gum, 4 mg • stop smoking aid

Gum

Original

4 mg

FOR THOSE WHO SMOKE THEIR FIRST CIGARETTE WITHIN 30 MINUTES OF WAKING UP.

If you smoke your first cigarette **MORE THAN 30 MINUTES** after waking up, use Nicorette® 2 mg Gum

110 PIECES, 4mg EACH

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29546XG



Principal Display Panel

NDC 0135-0466-02

Nicorette®

nicotine polacrilex gum, 2 mg • stop smoking aid

Gum

Coated

FOR BOLD FLAVOR

Cinnamon Surge™

2 mg

FOR THOSE WHO SMOKE THEIR FIRST CIGARETTE MORE THAN 30 MINUTES AFTER WAKING UP.

If you smoke your first cigarette **WITHIN 30 MINUTES** of waking up, use Nicorette 4mg Gum
100 PIECES, 2 mg EACH

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30214XG



Principal Display Panel

NDC 0135-0467-02

Nicorette®

nicotine polacrilex gum, 4 mg • stop smoking aid

Gum

Coated

FOR BOLD FLAVOR

Cinnamon Surge™

4 mg

FOR THOSE WHO SMOKE THEIR FIRST CIGARETTE WITHIN 30 MINUTES OF WAKING UP.

If you smoke your first cigarette **MORE THAN 30 MINUTES** after waking up, use Nicorette 2 mg Gum

100 PIECES, 4 mg EACH

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30215XG



Principal Display Panel

NDC 0135-0225-02

Nicorette®

nicotine polacrilex gum, 2 mg • stop smoking aid

Gum

Coated

FOR BOLD FLAVOR

Fresh Mint™

2 mg

FOR THOSE WHO SMOKE THEIR FIRST CIGARETTE MORE THAN 30 MINUTES AFTER WAKING UP.

If you smoke your first cigarette **WITHIN 30 MINUTES** of waking up, use Nicorette 4 mg Gum
100 PIECES, 2 mg EACH

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29547XI



Principal Display Panel

NDC 0135-0226-02

Nicorette®

nicotine polacrilex gum, 4 mg • stop smoking aid
Gum

Coated

FOR BOLD FLAVOR

Fresh Mint™

4 mg

FOR THOSE WHO SMOKE THEIR FIRST CIGARETTE WITHIN 30 MINUTES OF WAKING UP.

If you smoke your first cigarette **MORE THAN 30 MINUTES** after waking up, use Nicorette® 2 mg Gum

100 PIECES, 4 mg EACH

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29548XI



Principal Display Panel

NDC 0135-0229-04

Nicorette®

nicotine polacrilex gum, 2mg • stop smoking aid

Gum

Mint

2 mg

**FOR THOSE WHO SMOKE THEIR FIRST CIGARETTE MORE THAN 30 MINUTES
AFTER WAKING UP.**

If you smoke your first cigarette **WITHIN 30 MINUTES** of waking up, use Nicorette 4mg Gum

110 PIECES, 2mg EACH

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29552XG

NDC 0135-0229-04

Nicorette[®]

nicotine polacrilex gum, 2mg • stop smoking aid

Gum



FOR THOSE WHO SMOKE
THEIR FIRST CIGARETTE
MORE THAN 30 MINUTES
AFTER WAKING UP.

If you smoke your first cigarette
WITHIN 30 MINUTES of waking
up, use Nicorette 4mg Gum

Mint

110 PIECES, 2mg EACH

Principal Display Panel

NDC 0135-0230-04

Nicorette[®]

nicotine polacrilex gum, 4mg • stop smoking aid

Gum

Mint

4 mg

**FOR THOSE WHO SMOKE THEIR FIRST CIGARETTE WITHIN 30 MINUTES OF
WAKING UP.**

If you smoke your first cigarette **MORE THAN 30 MINUTES** after waking up, use Nicorette 2mg Gum

110 PIECES, 4mg EACH

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29553XG

Nicorette®

nicotine polacrilex gum, 4mg • stop smoking aid

Gum



4
mg

FOR THOSE WHO SMOKE
THEIR FIRST CIGARETTE
WITHIN 30 MINUTES
OF WAKING UP.

If you smoke your first
cigarette **MORE THAN**
30 MINUTES after waking
up, use Nicorette 2mg Gum

Mint

110 PIECES, 4mg EACH

Principal Display Panel

NDC 0135-0532-02

Nicorette

nicotine polacrilex gum, 2 mg • stop smoking aid

Gum

NEW FLAVOR

Coated FOR BOLD FLAVOR

***Spearmint Burst** with a hint of chamomile*

FOR THOSE WHO SMOKE THEIR FIRST CIGARETTE MORE THAN 30 MINUTES AFTER WAKING UP.

If you smoke your first cigarette **WITHIN 30 MINUTES** of waking up, use Nicorette 4 mg Gum
100 PIECES, 2 mg EACH

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101782XC



Principal Display Panel

NDC 0135-0533-02

Nicorette

nicotine polacrilex gum, 4 mg • stop smoking aid

Gum

Coated FOR BOLD FLAVOR

Spearmint Burst with a hint of chamomile

FOR THOSE WHO SMOKE THEIR FIRST CIGARETTE WITHIN 30 MINUTES OF WAKING UP.

If you smoke your first cigarette **MORE THAN 30 MINUTES** after waking up, use Nicorette 2 mg Gum

100 PIECES, 4 mg EACH

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101781XC



Principal Display Panel

NDC 0135-0355-03

Nicorette

nicotine polacrilex gum, 4 mg • stop smoking aid

Gum

Coated FOR BOLD FLAVOR

Spearmint Burst with a hint of chamomile

FOR THOSE WHO SMOKE THEIR FIRST CIGARETTE WITHIN 30 MINUTES OF WAKING UP.

If you smoke your first cigarette **MORE THAN 30 MINUTES** after waking up, use Nicorette 2 mg Gum

160 PIECES, 4 mg EACH

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105941XB



NICORETTE WHITE ICE MINT

nicotine polacrilex gum, chewing

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:0135-0474 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|----------|
| NICOTINE (UNII: 6M3C89ZY6R) (NICOTINE - UNII:6M3C89ZY6R) | NICOTINE | 2 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| POLACRILIN (UNII: RCZ785HI7S) | |
| ACESULFAME POTASSIUM (UNII: 23OV73Q5G9) | |
| CARNAUBA WAX (UNII: R12CBM0EIZ) | |
| HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO) | |
| MAGNESIUM OXIDE (UNII: 3A3U0GI71G) | |
| MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) | |
| PEPPERMINT OIL (UNII: AV092KU4JH) | |
| POLYSORBATE 80 (UNII: 6OZP39ZG8H) | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | |
| SODIUM CARBONATE (UNII: 45P3261C7T) | |
| SUCRALOSE (UNII: 96K6UQ3ZD4) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |
| XYLITOL (UNII: VCQ006KQ1E) | |

Product Characteristics

| | | | |
|----------|-----------------------|--------------|----------|
| Color | WHITE | Score | no score |
| Shape | SQUARE | Size | 15mm |
| Flavor | MINT (White Ice Mint) | Imprint Code | N2 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0135-0474-01 | 1 in 1 CARTON | 06/29/2009 | |
| 1 | | 20 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |
| 2 | NDC:0135-0474-02 | 1 in 1 CARTON | 06/29/2009 | |
| 2 | | 100 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |
| 3 | NDC:0135-0474-05 | 1 in 1 CARTON | 06/29/2009 | |
| 3 | | 160 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |
| 4 | NDC:0135-0474-08 | 20 in 1 CARTON; Type 0: Not a Combination Product | 06/29/2009 | |
| 5 | NDC:0135-0474-14 | 25 in 1 CARTON; Type 0: Not a Combination Product | 06/29/2009 | 08/01/2018 |
| 6 | NDC:0135-0474-15 | 8 in 1 PACKAGE | 06/29/2009 | 08/01/2018 |
| 6 | | 25 in 1 CARTON; Type 0: Not a Combination Product | | |
| 7 | NDC:0135-0474-17 | 1 in 1 CARTON | 06/29/2009 | |
| 7 | | 10 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |

| | | | | |
|----|------------------|---|------------|--|
| 8 | NDC:0135-0474-18 | 2 in 1 PACKAGE | 08/01/2014 | |
| 8 | | 10 in 1 CARTON | | |
| 8 | | 10 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |
| 9 | NDC:0135-0474-19 | 12 in 1 CARTON | 09/01/2018 | |
| 9 | | 10 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |
| 10 | NDC:0135-0474-20 | 18 in 1 CARTON | 12/03/2018 | |
| 10 | | 10 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| NDA | NDA018612 | 06/29/2009 | |

NICORETTE WHITE ICE MINT

nicotine polacrilex gum, chewing

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:0135-0475 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|----------|
| NICOTINE (UNII: 6M3C89ZY6R) (NICOTINE - UNII:6M3C89ZY6R) | NICOTINE | 4 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| POLACRILIN (UNII: RCZ785HI7S) | |
| ACESULFAME POTASSIUM (UNII: 23OV73Q5G9) | |
| CARNAUBA WAX (UNII: R12CBM0EIZ) | |
| D&C YELLOW NO. 10 (UNII: 35SW5USQ3G) | |
| ALUMINUM OXIDE (UNII: LM26O6933) | |
| HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO) | |
| MAGNESIUM OXIDE (UNII: 3A3U0GI71G) | |
| MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) | |
| PEPPERMINT OIL (UNII: AV092KU4JH) | |
| POLYSORBATE 80 (UNII: 6OZP39ZG8H) | |
| SODIUM CARBONATE (UNII: 45P3261C7T) | |
| SUCRALOSE (UNII: 96K6UQ3ZD4) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |
| XYLITOL (UNII: VCQ006KQ1E) | |

Product Characteristics

| | | | |
|-----------------|-----------------------|---------------------|----------|
| Color | WHITE (cream) | Score | no score |
| Shape | SQUARE | Size | 15mm |
| Flavor | MINT (White Ice Mint) | Imprint Code | N4 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|----|------------------|--|----------------------|--------------------|
| 1 | NDC:0135-0475-01 | 1 in 1 CARTON | 06/29/2009 | |
| 1 | | 20 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |
| 2 | NDC:0135-0475-02 | 1 in 1 CARTON | 06/29/2009 | |
| 2 | | 100 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |
| 3 | NDC:0135-0475-03 | 1 in 1 CARTON | 06/29/2009 | 08/01/2019 |
| 3 | | 190 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |
| 4 | NDC:0135-0475-05 | 1 in 1 CARTON | 06/29/2009 | |
| 4 | | 160 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |
| 5 | NDC:0135-0475-08 | 20 in 1 CARTON; Type 0: Not a Combination Product | 06/29/2009 | |
| 6 | NDC:0135-0475-14 | 25 in 1 CARTON; Type 0: Not a Combination Product | 06/29/2009 | 08/01/2018 |
| 7 | NDC:0135-0475-15 | 8 in 1 PACKAGE | 06/29/2009 | 08/01/2018 |
| 7 | | 25 in 1 CARTON; Type 0: Not a Combination Product | | |
| 8 | NDC:0135-0475-17 | 1 in 1 CARTON | 06/29/2009 | |
| 8 | | 10 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |
| 9 | NDC:0135-0475-18 | 2 in 1 PACKAGE | 08/01/2014 | |
| 9 | | 10 in 1 CARTON | | |
| 9 | | 10 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |
| 10 | NDC:0135-0475-19 | 12 in 1 CARTON | 09/01/2018 | |
| 10 | | 10 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |
| 11 | NDC:0135-0475-20 | 18 in 1 CARTON | 12/03/2018 | |
| 11 | | 10 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| NDA | NDA020066 | 06/29/2009 | |

NICORETTE ORIGINAL

nicotine polacrilex gum, chewing

Product Information

| | | | |
|---------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:0135-0157 |
|---------------------|----------------|---------------------------|---------------|

| | | | | |
|---|--|--|----------------------|--------------------|
| Route of Administration | | ORAL | | |
| | | | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | | Basis of Strength | Strength | |
| NICO TINE (UNII: 6M3C89ZY6R) (NICOTINE - UNII:6M3C89ZY6R) | | NICOTINE | 2 mg | |
| | | | | |
| Inactive Ingredients | | | | |
| Ingredient Name | | | Strength | |
| POLACRILIN (UNII: RCZ785HI7S) | | | | |
| GLYCERIN (UNII: PDC6A3C0OX) | | | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | | |
| SODIUM CARBONATE (UNII: 45P3261C7T) | | | | |
| SORBITOL (UNII: 506T60A25R) | | | | |
| | | | | |
| Product Characteristics | | | | |
| Color | WHITE (beige) | Score | no score | |
| Shape | SQUARE | Size | 14mm | |
| Flavor | | Imprint Code | | |
| Contains | | | | |
| | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:0135-0157-07 | 1 in 1 CARTON | 06/29/2009 | |
| 1 | | 110 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |
| 2 | NDC:0135-0157-10 | 1 in 1 CARTON | 06/29/2009 | |
| 2 | | 170 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |
| 3 | NDC:0135-0157-11 | 1 in 1 CARTON | 06/29/2009 | |
| 3 | | 200 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |
| 4 | NDC:0135-0157-12 | 1 in 1 CARTON | 06/29/2009 | 08/01/2019 |
| 4 | | 220 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |
| | | | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | | Marketing Start Date | Marketing End Date |
| NDA | NDA018612 | | 06/29/2009 | |

NICORETTE ORIGINAL

nicotine polacrilex gum, chewing

| Product Information | | | | |
|--|--|--|----------------------|--------------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:0135-0158 | |
| Route of Administration | ORAL | | | |
| | | | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | | Basis of Strength | Strength | |
| NICOTINE (UNII: 6M3C89ZY6R) (NICOTINE - UNII:6M3C89ZY6R) | | NICOTINE | 4 mg | |
| | | | | |
| Inactive Ingredients | | | | |
| Ingredient Name | | | Strength | |
| POLACRILIN (UNII: RCZ785HI7S) | | | | |
| D&C YELLOW NO. 10 (UNII: 35SW5USQ3G) | | | | |
| GLYCERIN (UNII: PDC6A3C0OX) | | | | |
| SODIUM CARBONATE (UNII: 45P3261C7T) | | | | |
| SORBITOL (UNII: 506T60A25R) | | | | |
| | | | | |
| Product Characteristics | | | | |
| Color | WHITE (beige) | Score | no score | |
| Shape | SQUARE | Size | 14mm | |
| Flavor | | Imprint Code | | |
| Contains | | | | |
| | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:0135-0158-07 | 1 in 1 CARTON | 06/29/2009 | |
| 1 | | 110 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |
| 2 | NDC:0135-0158-10 | 1 in 1 CARTON | 06/29/2009 | |
| 2 | | 170 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |
| 3 | NDC:0135-0158-11 | 1 in 1 CARTON | 06/29/2009 | |
| 3 | | 200 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |
| 4 | NDC:0135-0158-12 | 1 in 1 CARTON | 06/29/2009 | 08/01/2019 |
| 4 | | 220 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |
| | | | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | | Marketing Start Date | Marketing End Date |
| NDA | NDA020066 | | 06/29/2009 | |

NICORETTE CINNAMON SURGE

nicotine polacrilex gum, chewing

| Product Information | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:0135-0466 |
| Route of Administration | ORAL | | |

| Active Ingredient/Active Moiety | | |
|--|-------------------|----------|
| Ingredient Name | Basis of Strength | Strength |
| NICOTINE (UNII: 6M3C89ZY6R) (NICOTINE - UNII:6M3C89ZY6R) | NICOTINE | 2 mg |

| Inactive Ingredients | |
|--|----------|
| Ingredient Name | Strength |
| POLACRILIN (UNII: RCZ785HI7S) | |
| ACACIA (UNII: 5C5403N26O) | |
| ACESULFAME POTASSIUM (UNII: 23OV73Q5G9) | |
| CARNAUBA WAX (UNII: R12CBM0EIZ) | |
| HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO) | |
| MAGNESIUM OXIDE (UNII: 3A3U0GI71G) | |
| MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) | |
| PEPPERMINT OIL (UNII: AV092KU4JH) | |
| POLYSORBATE 80 (UNII: 6OZP39ZG8H) | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | |
| SODIUM CARBONATE (UNII: 45P3261C7T) | |
| SUCRALOSE (UNII: 96K6UQ3ZD4) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |
| XYLITOL (UNII: VCQ006KQ1E) | |

| Product Characteristics | | | |
|-------------------------|----------|--------------|----------|
| Color | WHITE | Score | no score |
| Shape | SQUARE | Size | 15mm |
| Flavor | CINNAMON | Imprint Code | N2 |
| Contains | | | |

| Packaging | | | | |
|-----------|------------------|--|----------------------|--------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:0135-0466-01 | 1 in 1 CARTON | 06/29/2009 | |
| 1 | | 20 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |
| 2 | NDC:0135-0466-02 | 1 in 1 CARTON | 06/29/2009 | |
| 2 | | 100 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |
| 3 | NDC:0135-0466-03 | 1 in 1 CARTON | 06/29/2009 | |

| | | | | |
|---|------------------|--|------------|------------|
| 3 | | 190 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |
| 4 | NDC:0135-0466-05 | 1 in 1 CARTON | 06/29/2009 | |
| 4 | | 160 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |
| 5 | NDC:0135-0466-07 | 1 in 1 CARTON | 06/29/2009 | |
| 5 | | 40 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |
| 6 | NDC:0135-0466-08 | 20 in 1 CARTON; Type 0: Not a Combination Product | 06/29/2009 | |
| 7 | NDC:0135-0466-14 | 25 in 1 CARTON; Type 0: Not a Combination Product | 06/29/2009 | 08/01/2018 |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| NDA | NDA018612 | 06/29/2009 | |

NICORETTE CINNAMON SURGE

nicotine polacrilex gum, chewing

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:0135-0467 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|----------|
| NICOTINE (UNII: 6M3C89ZY6R) (NICOTINE - UNII:6M3C89ZY6R) | NICOTINE | 4 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| POLACRILIN (UNII: RCZ785HI7S) | |
| ACACIA (UNII: 5C5403N26O) | |
| ACESULFAME POTASSIUM (UNII: 23OV73Q5G9) | |
| CARNAUBA WAX (UNII: R12CBM0EIZ) | |
| D&C YELLOW NO. 10 (UNII: 35SW5USQ3G) | |
| ALUMINUM OXIDE (UNII: LM26O6933) | |
| HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO) | |
| MAGNESIUM OXIDE (UNII: 3A3U0GI71G) | |
| MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) | |
| PEPPERMINT OIL (UNII: AV092KU4JH) | |
| POLYSORBATE 80 (UNII: 6OZP39ZG8H) | |
| SODIUM CARBONATE (UNII: 45P3261C7T) | |
| SUCRALOSE (UNII: 96K6UQ3ZD4) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |
| XYLITOL (UNII: VCQ006KQ1E) | |

Product Characteristics

| | | | |
|-----------------|---------------|---------------------|----------|
| Color | WHITE (cream) | Score | no score |
| Shape | SQUARE | Size | 15mm |
| Flavor | CINNAMON | Imprint Code | N4 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0135-0467-01 | 1 in 1 CARTON | 06/29/2009 | |
| 1 | | 20 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |
| 2 | NDC:0135-0467-02 | 1 in 1 CARTON | 06/29/2009 | |
| 2 | | 100 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |
| 3 | NDC:0135-0467-05 | 1 in 1 CARTON | 06/29/2009 | |
| 3 | | 160 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |
| 4 | NDC:0135-0467-07 | 1 in 1 CARTON | 06/29/2009 | |
| 4 | | 40 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |
| 5 | NDC:0135-0467-08 | 20 in 1 CARTON; Type 0: Not a Combination Product | 06/29/2009 | |
| 6 | NDC:0135-0467-14 | 25 in 1 CARTON; Type 0: Not a Combination Product | 06/29/2009 | 08/01/2018 |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| NDA | NDA020066 | 06/29/2009 | |

NICORETTE FRESH MINT

nicotine polacrilex gum, chewing

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:0135-0225 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|----------|
| NICOTINE (UNII: 6M3C89ZY6R) (NICOTINE - UNII:6M3C89ZY6R) | NICOTINE | 2 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| POLACRILIN (UNII: RCZ785HI7S) | |
| ACACIA (UNII: 5C5403N26O) | |
| ACESULFAME POTASSIUM (UNII: 23OV73Q5G9) | |
| CARNAUBA WAX (UNII: R12CBM0EIZ) | |
| MAGNESIUM OXIDE (UNII: 3A3U0GI71G) | |
| MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) | |
| PEPPERMINT OIL (UNII: AV092KU4JH) | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | |
| SODIUM CARBONATE (UNII: 45P3261C7T) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |
| XYLITOL (UNII: VCQ006KQ1E) | |

Product Characteristics

| | | | |
|----------|-------------------|--------------|----------|
| Color | WHITE | Score | no score |
| Shape | SQUARE | Size | 15mm |
| Flavor | MINT (Fresh Mint) | Imprint Code | N2 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0135-0225-02 | 1 in 1 CARTON | 06/29/2009 | |
| 1 | | 100 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |
| 2 | NDC:0135-0225-03 | 1 in 1 CARTON | 06/29/2009 | 08/01/2019 |
| 2 | | 190 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |
| 3 | NDC:0135-0225-08 | 20 in 1 CARTON; Type 0: Not a Combination Product | 06/29/2009 | 08/01/2019 |
| 4 | NDC:0135-0225-14 | 25 in 1 CARTON; Type 0: Not a Combination Product | 06/29/2009 | 08/01/2018 |
| 5 | NDC:0135-0225-15 | 8 in 1 PACKAGE | 06/29/2009 | 08/01/2018 |
| 5 | | 25 in 1 CARTON; Type 0: Not a Combination Product | | |
| 6 | NDC:0135-0225-17 | 2 in 1 PACKAGE | 08/01/2014 | |
| 6 | | 10 in 1 CARTON | | |
| 6 | | 10 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| NDA | NDA018612 | 06/29/2009 | |

NICORETTE FRESH MINT

nicotine polacrilex gum, chewing

Product Information

| | | | | |
|--|---------------------|--|----------------------|--------------------|
| Product Type | | HUMAN OTC DRUG | Item Code (Source) | NDC:0135-0226 |
| Route of Administration | | ORAL | | |
| | | | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | | | Basis of Strength | Strength |
| NICOTINE (UNII: 6M3C89ZY6R) (NICOTINE - UNII:6M3C89ZY6R) | | | NICOTINE | 4 mg |
| | | | | |
| Inactive Ingredients | | | | |
| Ingredient Name | | | | Strength |
| POLACRILIN (UNII: RCZ785HI7S) | | | | |
| ACACIA (UNII: 5C5403N26O) | | | | |
| ACESULFAME POTASSIUM (UNII: 23OV73Q5G9) | | | | |
| CARNAUBA WAX (UNII: R12CBM0EIZ) | | | | |
| D&C YELLOW NO. 10 (UNII: 35SW5USQ3G) | | | | |
| ALUMINUM OXIDE (UNII: LM26O6933) | | | | |
| MAGNESIUM OXIDE (UNII: 3A3U0GI71G) | | | | |
| MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) | | | | |
| PEPPERMINT OIL (UNII: AV092KU4JH) | | | | |
| SODIUM CARBONATE (UNII: 45P3261C7T) | | | | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | | | | |
| XYLITOL (UNII: VCQ006KQ1E) | | | | |
| | | | | |
| Product Characteristics | | | | |
| Color | WHITE (light cream) | | Score | no score |
| Shape | SQUARE | | Size | 15mm |
| Flavor | MINT (Fresh Mint) | | Imprint Code | N4 |
| Contains | | | | |
| | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:0135-0226-02 | 1 in 1 CARTON | 06/29/2009 | |
| 1 | | 100 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |
| 2 | NDC:0135-0226-03 | 1 in 1 CARTON | 06/29/2009 | 08/01/2019 |
| 2 | | 190 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |
| 3 | NDC:0135-0226-08 | 20 in 1 CARTON; Type 0: Not a Combination Product | 06/29/2009 | 08/01/2019 |
| 4 | NDC:0135-0226-14 | 25 in 1 CARTON; Type 0: Not a Combination Product | 06/29/2009 | 08/01/2018 |
| 5 | NDC:0135-0226-15 | 8 in 1 PACKAGE | 06/29/2009 | 08/01/2018 |
| 5 | | 25 in 1 CARTON; Type 0: Not a Combination Product | | |
| 6 | NDC:0135-0226-17 | 2 in 1 PACKAGE | 08/01/2014 | |
| 6 | | 10 in 1 CARTON | | |

| | | | |
|------------------------------|---|-----------------------------|---------------------------|
| 6 | 10 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |
| Marketing Information | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| NDA | NDA020066 | 06/29/2009 | |

| | | | | |
|--|------------------|---|----------------------|--------------------|
| NICORETTE MINT | | | | |
| nicotine polacrilex gum, chewing | | | | |
| | | | | |
| Product Information | | | | |
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:0135-0229 | |
| Route of Administration | ORAL | | | |
| | | | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | | Basis of Strength | Strength | |
| NICOTINE (UNII: 6M3C89ZY6R) (NICOTINE - UNII:6M3C89ZY6R) | | NICOTINE | 2 mg | |
| | | | | |
| Inactive Ingredients | | | | |
| Ingredient Name | | | Strength | |
| POLACRILIN (UNII: RCZ785HI7S) | | | | |
| ACESULFAME POTASSIUM (UNII: 23OV73Q5G9) | | | | |
| MAGNESIUM OXIDE (UNII: 3A3U0GI71G) | | | | |
| MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) | | | | |
| PEPPERMINT OIL (UNII: AV092KU4JH) | | | | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | | | | |
| SODIUM CARBONATE (UNII: 45P3261C7T) | | | | |
| XYLITOL (UNII: VCQ006KQ1E) | | | | |
| | | | | |
| Product Characteristics | | | | |
| Color | BROWN (beige) | Score | no score | |
| Shape | SQUARE | Size | 14mm | |
| Flavor | MINT | Imprint Code | | |
| Contains | | | | |
| | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:0135-0229-03 | 1 in 1 CARTON | 06/29/2009 | 08/01/2019 |
| 1 | | 50 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |
| 2 | NDC:0135-0229-04 | 1 in 1 CARTON | 06/29/2009 | 08/01/2019 |

| | | | | |
|---|------------------|--|------------|--|
| 2 | | 110 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |
| 3 | NDC:0135-0229-05 | 1 in 1 CARTON | 06/29/2009 | |
| 3 | | 170 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| NDA | NDA018612 | 06/29/2009 | |

NICORETTE MINT

nicotine polacrilex gum, chewing

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:0135-0230 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|----------|
| NICOTINE (UNII: 6M3C89ZY6R) (NICOTINE - UNII:6M3C89ZY6R) | NICOTINE | 4 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| POLACRILIN (UNII: RCZ785HI7S) | |
| ACESULFAME POTASSIUM (UNII: 23OV73Q5G9) | |
| D&C YELLOW NO. 10 (UNII: 35SW5USQ3G) | |
| ALUMINUM OXIDE (UNII: LM26O6933) | |
| MAGNESIUM OXIDE (UNII: 3A3U0GI71G) | |
| MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) | |
| PEPPERMINT OIL (UNII: AV092KU4JH) | |
| SODIUM CARBONATE (UNII: 45P3261C7T) | |
| XYLITOL (UNII: VCQ006KQ1E) | |

Product Characteristics

| | | | |
|----------|---------------|--------------|----------|
| Color | BROWN (beige) | Score | no score |
| Shape | SQUARE | Size | 14mm |
| Flavor | MINT | Imprint Code | |
| Contains | | | |

Packaging

| | | | |
|--|--|-----------------|--|
| | | Marketing Start | |
|--|--|-----------------|--|

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0135-0230-03 | 1 in 1 CARTON | 06/29/2009 | |
| 1 | | 50 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |
| 2 | NDC:0135-0230-04 | 1 in 1 CARTON | 06/29/2009 | 08/01/2019 |
| 2 | | 110 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |
| 3 | NDC:0135-0230-05 | 1 in 1 CARTON | 06/29/2009 | |
| 3 | | 170 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| NDA | NDA020066 | 06/29/2009 | |

NICORETTE SPEARMINT BURST

nicotine polacrilex gum, chewing

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:0135-0532 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|----------|
| NICOTINE (UNII: 6M3C89ZY6R) (NICOTINE - UNII:6M3C89ZY6R) | NICOTINE | 2 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| POLACRILIN (UNII: RCZ785HI7S) | |
| ACACIA (UNII: 5C5403N26O) | |
| ACESULFAME POTASSIUM (UNII: 23OV73Q5G9) | |
| CARNAUBA WAX (UNII: R12CBM0EIZ) | |
| HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO) | |
| MAGNESIUM OXIDE (UNII: 3A3U0GI71G) | |
| MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) | |
| PEPPERMINT OIL (UNII: AV092KU4JH) | |
| POLYSORBATE 80 (UNII: 6OZP39ZG8H) | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | |
| SODIUM CARBONATE (UNII: 45P3261C7T) | |
| SUCRALOSE (UNII: 96K6UQ3ZD4) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |
| XYLITOL (UNII: VCQ006KQ1E) | |

| Product Characteristics | | | |
|-------------------------|---------------|--------------|----------|
| Color | WHITE (beige) | Score | no score |
| Shape | SQUARE | Size | 15mm |
| Flavor | SPEARMINT | Imprint Code | N2 |
| Contains | | | |

| Packaging | | | | |
|-----------|------------------|---|----------------------|--------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:0135-0532-02 | 10 in 1 CARTON | 09/13/2017 | |
| 1 | | 10 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |
| 2 | NDC:0135-0532-03 | 16 in 1 CARTON | 09/13/2017 | |
| 2 | | 10 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |
| 3 | NDC:0135-0532-12 | 2 in 1 PACKAGE | 03/01/2018 | |
| 3 | | 10 in 1 CARTON | | |
| 3 | | 10 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |
| 4 | NDC:0135-0532-13 | 12 in 1 CARTON | 09/01/2018 | |
| 4 | | 10 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |
| 5 | NDC:0135-0532-14 | 18 in 1 CARTON | 12/03/2018 | |
| 5 | | 10 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |

| Marketing Information | | | |
|-----------------------|--|----------------------|--------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| NDA | NDA018612 | 09/13/2017 | |

NICORETTE SPEARMINT BURST

nicotine polacrilex gum, chewing

| Product Information | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:0135-0533 |
| Route of Administration | ORAL | | |

| Active Ingredient/Active Moiety | | |
|--|-------------------|----------|
| Ingredient Name | Basis of Strength | Strength |
| NICOTINE (UNII: 6M3C89ZY6R) (NICOTINE - UNII:6M3C89ZY6R) | NICOTINE | 4 mg |

| Inactive Ingredients | |
|---|----------|
| Ingredient Name | Strength |
| POLACRILIN (UNII: RCZ785HI7S) | |
| ACACIA (UNII: 5C5403N26O) | |
| ACESULFAME POTASSIUM (UNII: 23OV73Q5G9) | |

| | |
|--|--|
| CARNAUBA WAX (UNII: R12CBM0EIZ) | |
| D&C YELLOW NO. 10 (UNII: 35SW5USQ3G) | |
| HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO) | |
| MAGNESIUM OXIDE (UNII: 3A3U0GI71G) | |
| MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) | |
| PEPPERMINT OIL (UNII: AV092KU4JH) | |
| POLYSORBATE 80 (UNII: 6OZP39ZG8H) | |
| SODIUM CARBONATE (UNII: 45P3261C7T) | |
| SUCRALOSE (UNII: 96K6UQ3ZD4) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |
| XYLITOL (UNII: VCQ006KQ1E) | |

Product Characteristics

| | | | |
|----------|-----------|--------------|----------|
| Color | YELLOW | Score | no score |
| Shape | SQUARE | Size | 15mm |
| Flavor | SPEARMINT | Imprint Code | N4 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:0135-0533-02 | 10 in 1 CARTON | 09/13/2017 | |
| 1 | | 10 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |
| 2 | NDC:0135-0533-12 | 2 in 1 PACKAGE | 03/01/2018 | |
| 2 | | 10 in 1 CARTON | | |
| 2 | | 10 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |
| 3 | NDC:0135-0533-13 | 12 in 1 CARTON | 09/01/2018 | |
| 3 | | 10 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |
| 4 | NDC:0135-0533-14 | 18 in 1 CARTON | 12/03/2018 | |
| 4 | | 10 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| NDA | NDA020066 | 09/13/2017 | |

NICORETTE SPEARMINT BURST

nicotine polacrilex gum, chewing

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:0135-0355 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | | Basis of Strength | Strength | |
|--|--|---|----------------------|--------------------|
| NICOTINE (UNII: 6M3C89ZY6R) (NICOTINE - UNII:6M3C89ZY6R) | | NICOTINE | 4 mg | |
| | | | | |
| Inactive Ingredients | | | | |
| Ingredient Name | | | Strength | |
| POLACRILIN (UNII: RCZ785HI7S) | | | | |
| ACACIA (UNII: 5C5403N26O) | | | | |
| ACESULFAME POTASSIUM (UNII: 23OV73Q5G9) | | | | |
| CARNAUBA WAX (UNII: R12CBM0EIZ) | | | | |
| D&C YELLOW NO. 10 (UNII: 35SW5USQ3G) | | | | |
| HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO) | | | | |
| MAGNESIUM OXIDE (UNII: 3A3U0GI71G) | | | | |
| MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) | | | | |
| PEPPERMINT OIL (UNII: AV092KU4JH) | | | | |
| POLYSORBATE 80 (UNII: 6OZP39ZG8H) | | | | |
| SODIUM CARBONATE (UNII: 45P3261C7T) | | | | |
| SUCRALOSE (UNII: 96K6UQ3ZD4) | | | | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | | | | |
| XYLITOL (UNII: VCQ006KQ1E) | | | | |
| | | | | |
| Product Characteristics | | | | |
| Color | YELLOW | Score | no score | |
| Shape | SQUARE | Size | 15mm | |
| Flavor | SPEARMINT | Imprint Code | N4 | |
| Contains | | | | |
| | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:0135-0355-03 | 16 in 1 CARTON | 09/13/2017 | |
| 1 | | 10 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |
| | | | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | | Marketing Start Date | Marketing End Date |
| NDA | NDA020066 | | 09/13/2017 | |

Labeler - GlaxoSmithKline Consumer Healthcare Holdings (US) LLC (079944263)